DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 16, 2015

Boston Scientific Corporation
Carter Navarro
Manager, Regulatory Affairs
100 Boston Scientific Way
Mail Stop M-11
Marlborough, MA 01752

Re: K142922
Trade/Device Name: SpyGlass DS Direct Visualization System
Regulation Number: 21 CFR 876.1500
Regulation Name: Gastroenterology/Urology
Regulatory Class: Class II
Product Code: FBN, NTN, KQM
Dated: December 19, 2014
Received: December 22, 2014

Dear Carter Navarro,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142922

Device Name
SpyGlass DS Direct Visualization System

Indications for Use *(Describe)*

The SpyGlass DS Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter and the SpyGlass DS Digital Controller.

The SpyScope DS Access and Delivery Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for SpyGlass™ DS Direct Visualization System

1. Submitter

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Date Prepared: October 7, 2014

2. Device

Trade Name:	SpyGlass DS Direct Visualization System
Common Name:	Choledochoscope and accessories, flexible/rigid; Surgical camera and accessories; LED light source
Product Code:	FBN, KQM, NTN
Device Class and Panel:	Class II, Gastroenterology/Urology (FBN, NTN) Class I, General and plastic surgery (KQM)
Classification Regulation:	21 CFR 876.1500 (FBN, NTN) 21 CFR 878.4160 (KQM)

3. Predicate Devices

Trade Name:	ACMI DUR-Digital Ureteroscope and Choledochoscope System
Manufacturer:	ACMI Corporation
Clearance Number:	K060269
Common Name:	Choledochoscope and accessories, flexible/rigid
Product Code:	FBN
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Trade Name:	SpyScope Access and Delivery Catheter
Manufacturer:	Boston Scientific Corporation
Clearance Number:	K090170

Common Name:	Mini endoscope, gastroenterology-urology
Product Code:	ODF
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Trade Name:	SpyGlass Direct Visualization Probe/Ocular
Manufacturer:	Boston Scientific Corporation
Clearance Number:	K052194
Common Name:	Endoscope and/or accessories
Product Code:	KOG
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Trade Name:	Olympus XCHF-B180Y1 Choledochoscope
Manufacturer:	Olympus Medical Systems Corporation
Clearance Number:	K080586
Common Name:	Choledochoscope and accessories, flexible/rigid
Product Code:	FBN
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

Trade Name:	Stryker LED Light Source
Manufacturer:	Stryker Endoscopy
Clearance Number:	K082813
Common Name:	Light source, fiberoptic, routine
Product Code:	FCW
Device Class and Panel:	Class II, Gastroenterology/Urology
Classification Regulation:	21 CFR 876.1500

4. Device Description

The SpyGlass DS Direct Visualization System comprises two components: (1) the sterile, single-use SpyScope DS Access and Delivery Catheter ("Catheter") and (2) the SpyGlass DS Digital Controller (the "Controller").

The Catheter is a flexible video cholangiopancreatoscope, introduced into the pancreatico-biliary system via a duodenoscope. The Catheter comprises a handle, an insertion tube, and a connection cable. The handle includes two articulation control knobs, a lever to lock the control knobs in place, connectors for irrigation and aspiration, a working channel port, and a strap to attach the Catheter to a duodenoscope. The insertion tube contains one working channel for accessory devices and aspiration, two channels for irrigation, two optical fibers to transmit illumination from the Controller, and wiring to transmit video signals to the Controller. The bending section at the distal portion of the insertion tube is controlled by the user via the articulation control knobs on the handle. The distal end of the insertion tube contains an imaging sensor for capturing

video and transmitting it to the Controller, elements for transmitting illumination from the Controller, and the distal openings of the irrigation and working channels. The connection cable connects the Catheter handle to the Controller for transmitting illumination and video signals.

The Controller is an endoscopic video imaging system that combines the functionality of a camera and an LED light source. The Controller receives video signals from the Catheter, processes the video signals, and outputs video images to an attached monitor. The Controller also generates and controls the illumination transmitted to the distal end of the Catheter. The user interface of the Controller comprises a power button, a receptacle to connect the Catheter connection cable, buttons to turn illumination on or off and to control the illumination intensity, and an illumination intensity indicator. The Controller outputs video images to an attached monitor via DVI, VGA, or S-Video ports, and the user may select NTSC or PAL video formats according to the geographic region of use.

5. Indication for Use

The SpyGlass DS Direct Visualization System is indicated for use in diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS Direct Visualization System comprises two components: the SpyScope DS Access and Delivery Catheter and the SpyGlass DS Digital Controller.

The SpyScope DS Access and Delivery Catheter is intended to provide direct visualization and to guide both optical and accessory devices for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

The SpyGlass DS Digital Controller is intended to provide illumination and receive, process, and output images from the SpyScope DS Access and Delivery Catheter for diagnostic and therapeutic applications during endoscopic procedures in the pancreatico-biliary system including the hepatic ducts.

6. Technological Characteristics

The proposed SpyGlass DS Direct Visualization System shares similar design features and functions with the predicate devices.

The proposed device and predicate ACMI DUR-Digital Ureteroscope and Choledochoscope System share similar indications for use, both being intended for use for examination of the bile duct, and facilitating diagnostic and therapeutic procedures in the bile duct. The proposed device and predicate ACMI DUR-Digital Ureteroscope and

Choledochoscope System share similar technological characteristics, including CMOS image sensors for visualization, light-emitting diodes (LEDs) for illumination (the light source is located in the handheld component of the predicate device), and similar video output capabilities. The differences in respect to the dimensions of the Catheter and location of the LEDs do not alter the suitability of the proposed device for its intended use.

In overall appearance, dimensions, and mechanical performance, the proposed SpyScope DS Access and Delivery Catheter is very similar to the SpyScope Access and Delivery Catheter, while adding the optical functionality of the SpyGlass Probe/Ocular. The minor dimensional differences between the proposed SpyScope DS Access and Delivery Catheter and the predicate SpyScope Access and Delivery Catheter do not raise new questions of safety or effectiveness for the proposed device's intended use in the pancreatico-biliary system. The applicable dimensions are within the range of the predicate Olympus XCHF-B180Y1 Choledochoscope, which has the same indications for use.

The proposed SpyGlass DS Digital Controller and the predicate Stryker LED Light Source share similar technological characteristics, both utilizing LEDs for illumination, and both offering brightness control.

7. Substantial Equivalence

A direct comparison of key characteristics demonstrates that the SpyGlass DS Direct Visualization System is substantially equivalent to the predicate devices in terms of intended use, technological characteristics, and performance characteristics. The SpyGlass DS Direct Visualization System is as safe and effective as the predicate devices.

8. Performance Data

Non-clinical testing was successfully performed on the proposed SpyGlass DS Direct Visualization System.

Performance testing (bench) was successfully completed to establish substantial equivalence between the proposed SpyGlass DS Direct Visualization System and the predicate devices. This testing included the following:

- Diameter
- Working length
- Working channel diameter
- Field of view
- Direction of view
- Resolution
- Articulation direction
- Articulation angle
- Surface and edges
- Irrigation and working channel system leakage
- Articulation reliability
- Attachment to duodenoscope reliability
- Duodenoscope compatibility

- Irrigation pump compatibility
- Accessory compatibility
- Image noise
- Video latency
- System frame rate
- Illumination intensity
- Default automatic light control setpoint
- Automatic light control response time
- Simultaneous video output

Biocompatibility of the SpyScope DS Access and Delivery Catheter was evaluated in accordance with ISO 10993-1:2009 for the body contact category of "surface – mucosal membrane" with a contact duration of "limited (≤24 hours)," and the following tests were performed: Cytotoxicity, Irritation, Sensitization, USP Physiochemical <661>, and Latex. All evaluation acceptance criteria were met.

Electrical safety and electromagnetic compatibility of the SpyGlass DS Direct Visualization System were evaluated in accordance with IEC 60601-1:2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012, IEC 60601-1-2:2007, and IEC 60601-2-18:2009. All evaluation acceptance criteria were met.

The results of non-clinical testing demonstrate that the SpyGlass DS Direct Visualization System is considered safe and effective for its intended use.

9. Conclusion

Boston Scientific has demonstrated that the proposed SpyGlass DS Direct Visualization System is substantially equivalent to the currently marketed predicate devices.